Individual Safety Report

3562186-0-00-01

MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

FOR VOLUNTARY reporting by health professionals of adverse events and product problems

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Form Approved: OMB No. 0910-0291 Expires: 11/30/99
See OMB statement on reverse.

FDA Use Only

Triage unit sequence #: 128229

A. Patient information

1. Patient identifier: [redacted] In confidence

2. Age at time of event: 76 Years or Date of birth: [redacted]

3. Sex: ☑ female ☐ male

4. Weight: ____ lbs or ____ kgs

B. Adverse event or product problem

1. ☑ Adverse event and/or ☐ Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)
- ☐ death (mm/dd/yyyy)
- ☑ life-threatening
- ☑ hospitalization - initial or prolonged
- ☐ disability
- ☐ congenital anomaly
- ☑ required intervention to prevent permanent impairment/damage
- ☐ other:

3. Date of event (mm/dd/yyyy): 07/11/2000

4. Date of this report (mm/dd/yyyy): 08/30/2000

5. Describe event or problem

76yof with rheumatoid arthritis receiving prednisone, Arava, Percocet -one tab q4h prn-, and Tylenol -650 mg qid prn- -duration of use of acetaminophen-containing products is unclear- was admitted from outside hospital on 7/11/00 after increasing confusion, BP of 80/50, positive hemocult, ammonia level of 85, AST of > 4500, ALT of 1019, bilirubin of 1.2, alk phos of 195, PT greater than 33, albumin of 2.8, and with a pulse-ox reading of 96%. Patient had no prior history of alcohol use or liver disease. Patient was provided supportive therapy and treated with N-aceytlcysteine and Vitamin K. AST improved to 62, ALT to 78, alkaline phoshatase to 102 by 7/16. Bilirubin peaked at 2.4 and decreased to 1.0 by 7/26/00.

6. Relevant tests/laboratory data, including dates

BP of 80/50, positive hemocult, ammonia level of 85, AST of > 4500, ALT of 1019, bilirubin of 1.2, alk phos of 195, PT greater than 33, albumin of 2.8, and with a pulse-ox reading of 96%. After treatment and discontination of suspect drugs AST improved to 62, ALT to 78, alkaline phoshatase to 102 by 7/18. Bilirubin peaked at 2.4 and decreased to 1.0 by 7/26/00.

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

Past medical history of rheumatoid arthritis, history of osteoarthritis involving the lumbar spine, status postdecompression and fusion of the lumbar spine, history of COPD, history of systemic hypertension, status post right tibial fracture. Past surgical history: arthroplasties of both knees and ORIF.

C. Suspect medication(s)

1. Name (Product Name) / (Labeled Strength) / (Mfr/Labeler)
- #1 Arava / 20mg / Hoechst Marion Roussel
- #2 Acetaminophen / 325mg / Unknown

2. Dose/Frequency/Route used
- #1 20mg / daily / Oral
- #2 ~975m g / q 4 to 6 / Oral

3. Therapy dates (if unknown, give duration) From / To (or best estimate)
- #1 07/12/1999 - 07/12/2000
- #2 02/01/2000 - 07/12/2000

4. Diagnosis for use (separate indications with commas)
- #1 Rheumatoid Arthritis
- #2 Pain

5. Event abated after use stopped or dose reduced
- #1 ☑ yes ☐ no ☐ doesn't apply
- #2 ☑ yes ☐ no ☐ doesn't apply

6. Lot # (if known)
- #1
- #2

7. Exp. date (if known)
- #1
- #2

8. Event reappeared after reintroduction
- #1 ☐ yes ☐ no ☑ doesn't apply
- #2 ☐ yes ☐ no ☑ doesn't apply

9. NDC # (for product problems only)
- -
- -

10. Concomitant medical products and therapy dates (exclude treatment of event)

MEDICATIONS ON TRANSFER: Duragesic patch, 50 mg every 72 hours; Calcium carbonate 500 mg p.o. q. day; Magnesium oxide 400 mg

D. Suspect medical device

1. Brand name

2. Type of device

3. Manufacturer name & address

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4. Operator of device
- ☐ health professional
- ☐ lay user/patient
- ☐ other

5. Expiration date (mm/dd/yyyy)

6.
- model #
- catalog #
- serial #
- lot #
- other #

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7. If implanted, give date (mm/dd/yyyy)

8. If explanted, give date (mm/dd/yyyy)

9. Device available for evaluation? (Do not send device to FDA)
☐ yes ☐ no ☐ returned to manufacturer on ____ (mm/dd/yyyy)

10. Concomitant medical products and therapy dates (exclude treatment of event)

E. Reporter (see confidentiality section on back)

1. Name [redacted] RPh

phone #: [redacted]

4. University of [redacted] Medical Center; [redacted]

[redacted]

United States

2. Health professional? ☑ yes ☐ no

3. Occupation: Pharmacist

4. Also reported to
- ☐ manufacturer
- ☐ user facility
- ☐ distributor

5. If you do not want your identity disclosed to the manufacturer, place an "X" in this box. ☑

FDA

Mail to: MEDWATCH, 5600 Fishers Lane, Rockville, MD 20852-9787

or FAX to: 1-800-FDA-0178

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FDA Form 3500

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

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C10. Concomitant medical products and therapy dates continued

p.o. q.day; Prednisone 5 mg p.o. q. day; Paxil 40 mg p.o. q. day; Prinivil 5 mg p.o. q. day; Zantac 150 mg p.o. q. day; Colace 1 p.o. b.i.d.

D10. Concomitant medical products and therapy dates continued

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